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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

PABBAN DEVELOPMENT, INC.,

Plaintiff,

vs.

KYPHON SÀRL, MEDTRONIC, INC., AND DOES 1-100,

Defendants.

KYPHON SÀRL and MEDTRONIC, INC.,

Counterclaimants,

vs.

PABBAN DEVELOPMENT, INC., BIO-MEDICAL DEVICES, INC., BIO-MEDICAL DEVICES INTERNATIONAL, INC., and HARRY N. HERBERT,

Counterdefendants.

No.: SACV 10-533 CJC (RNBx)

MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO MOTION TO DISMISS KYPHON SÀRL AND MEDTRONIC, INC.'S AMENDED COUNTERCLAIM

Date: August 8, 2011
Time: 1:30 p.m.
Place: Courtroom 6

Honorable Cormac J. Carney

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I

Introduction

This case involves the decision of Pabban Development, Inc. Bio-Medical Devices, Inc., Bio-Medical Devices International, Inc. and Harry N. Herbert (collectively "Pabban") to cut corners and conceal material facts in order to collect millions of dollars from Kyphon Sàrl ("Kyphon") for a medical device called the Natrix System that Pabban falsely represented was market ready. Instead of disclosing that the Natrix System contained design defects that rendered it unsafe for use on patients and unmarketable, Pabban falsely represented to Kyphon that the Natrix System was "free from defects" and suitable for its "intended and labeled purpose." In doing so, Pabban not only breached the Asset Purchase Agreement ("APA") executed by the parties, but committed fraud.

Because these facts cannot be truthfully denied, Pabban's motion to dismiss attempts to rely on selective extrinsic evidence to demonstrate that the defects were disclosed to Kyphon in the schedules to the APA. This new theory – that the Natrix System was defective but the defects were disclosed – is expressly contradicted by Pabban's statement in its first amended complaint that the Natrix System was "ready for use with patients" prior to the closing of the APA. *See* Docket No. 34 at 3:28. Moreover, a close examination of Pabban's evidence reveals that Pabban actively concealed the dangerous saline leaks that made the Natrix System impossible to sterilize and therefore unsafe for use on patients until *after* it received more than $18 million from Kyphon.

Specifically, Pabban points to Schedule 3.1.1 of the APA, which relates to a test conducted to determine the "shelf life" of the product, not saline leaks. In that schedule, Pabban represented to Kyphon that a six month shelf life study of the Natrix System had been "completed" with no negative results. In other words, Pabban affirmatively represented to Kyphon that after sitting on the equivalent of a shelf in a

doctor's office for six months, the Natrix System remained sterile and ready for use with patients. That representation – that the Natrix System was "free from defects" and "ready for use" – is consistent with other documents Pabban provided to Kyphon, including documents Pabban provided to Kyphon more than two months before the APA closed that stated the saline leaks were corrected and "closed." In other words, because the evidence reveals that Pabban sold Kyphon a defective medical device and took steps to conceal the truth, Pabban is liable not just for breach of contract, but also fraud.

II

Facts

Pabban Development, Inc., Bio-Medical Devices, Inc. ("BMD") and Bio-Medical Devices International, Inc. ("BMDI") are affiliated companies, all of which are owned or controlled by Harry N. Herbert. Docket No. 43 (Amended Counterclaim) at ¶¶ 1-4. Specifically, Herbert is the Chief Executive Officer of Pabban and is responsible for the for the day-to-day operations of Pabban, BMD and BMDI. *Id.* at ¶¶ 5-6.

Kyphon Sàrl ("Kyphon") sells products used in the treatment of spinal fractures. *Id.* at ¶ 7. In appropriate circumstances, such fractures may be treated by injecting bone cement into the vertebra in the spine and filling the cavity. *Id.* The cement reinforces the walls of the vertebra, which prevents compression. *Id.* The medical device used to inject the cement into the vertebra is known as a "bone filler device." *Id.*

In late 2007, Kyphon was in the very early stages of developing an improved "bone filler device." *Id.* at ¶ 9. However, Kyphon expected that this potential new offering would not be market-ready until at least May 2009 – significantly after it anticipated its competition would offer similar devices for sale.

Id. If those competitors beat Kyphon to the market, they would obtain a "first to market" advantage. *Id.* The "first to market" advantage is critical in the medical device industry because even a several month head start can significantly damage a competitor's potential market share. *Id.* Based in part on the fact that its potential new offering would not be "market-ready" until May 2009 and its competitors were farther along in the development process, Kyphon was interested in purchasing a market-ready product to avoid losing critical market share. *Id.*

BMD, BMDI and Pabban had developed a "bone filler device," which was called the Natrix Bone Cement Delivery System ("Natrix System"). *Id.* at ¶ 10. BMD and BMDI owned the tooling for the Natrix System, Pabban owned the assets related to the product, and an affiliate of Pabban called Syntech International, Inc. ("Syntech") manufactured the product. *Id.* Kyphon became aware of the Natrix System and communicated to Pabban and Herbert an interest in learning more about it to determine if Kyphon should continue to develop its own product or purchase the market-ready Natrix System. *Id.*

In November 2007, Kyphon met with Pabban, BMD, BMDI, and Herbert at BMD and BMDI's facility. *Id.* at ¶ 12. At that meeting, Pabban, BMD and BMDI not only demonstrated the Natrix System, but Herbert represented that the product had been used successfully in 30-40 surgical procedures and had been through at least eight rounds of marketing trials. *Id.* Representatives of Kyphon, including Kyphon's CEO, Bob White, told Herbert that if Kyphon purchased the Natrix System, it intended to launch the Natrix System at the prestigious and very important North American Spine Society conference in October 2008. *Id.* Herbert, on behalf of Pabban, BMD and BMDI, repeatedly assured Kyphon that the Natrix System was ready for market. *Id.*

In addition to representing to Kyphon that the Natrix System was ready for market, Pabban, BMD, BMDI, and Herbert represented to Kyphon that:

- If BMD and BMDI did not sell Natrix to Kyphon, BMD and

BMDI would start selling the product "within 30-45 days."

- BMD and BMDI planned to release Natrix "by end of March [2008]."
- As BMD and BMDI moved forward "with our marketing trials and production processes to our April 2 [2008] market release, we continue to validate the NATRIX market capabilities."
- Natrix is an "Immediately Accretive class one device, production-ready." *Id.* at ¶ 13.

After these initial meetings, Kyphon conducted an "on-site" due diligence session at BMD and BMDI's facility on May 22-23, 2008. *Id.* at ¶ 14. Kyphon conducted a second (and final) on-site due diligence session on June 12, 2008. *Id.* On August 7, 2008, Kyphon and Pabban closed an Asset Purchase Agreement ("APA") that had been previously entered into. *Id.* at ¶ 15.

After the APA closed, Kyphon learned that the Natrix System was unmerchantable and defective at the time Kyphon purchased it from Pabban. *Id.* at ¶ 17. The device uses a hydraulic delivery system to push bone cement through the delivery tube. *Id.* Saline fluid resides in a polyurethane bag inside the handle of the device. *Id.* In August 2008, after the APA closed, Kyphon received its first shipments of Natrix devices manufactured by Syntech. *Id.* Kyphon thereafter discovered fluid inside the packaging, which suggested the devices were leaking saline. *Id.* After conducting an investigation, Kyphon determined that two defects caused the leaks. *Id.* First, the seams or "welds" on the saline bag were weak and subject to splitting. *Id.* Second, the manner in which the bag was sealed to the device with an O-ring allowed saline to leak between the bag and the O-ring. *Id.* Kyphon had no way of knowing of the leaks prior to the closing of the APA. *Id.* In fact, Pabban, BMD, BMDI and Herbert took steps to conceal the leaks from Kyphon. *Id.*

In May 2008 (months prior to the closing of the APA), Pabban provided Kyphon with a copy of Pabban's Design Failure Mode and Effects Analysis

("DFMEA") and Process Failure Mode and Effects Analysis ("PFMEA"). *Id.* at ¶ 18. These documents, which are standard in the medical device industry, track problems with a device during development and document how and when the problems were solved. *Id.* While the documents note pre-closing leaks associated with the O-ring and saline bag, they represent that both issues were corrected and the matters were "closed" on May 20, 2008 – just prior to Kyphon's first due diligence visit. *Id.*

After the closing, Kyphon misplaced the disk that contained the Design History File ("DHF") that Pabban provided to Kyphon prior to the closing. *Id.* at ¶ 19. Kyphon then asked Pabban to provide another copy of the DHF, which Pabban did. *Id.* That second DHF, however, included a "Performance Qualification Protocol" that sets forth test parameters relating to the detection of saline leaks in the Natrix System. *Id.* That document is dated August 7, 2008 – the day of the closing and long after Kyphon had completed its due diligence. *Id.* The document shows that Pabban was still trying to correct dangerous saline leaks ***on the same day*** that Kyphon paid Pabban in excess of $18 million for a medical device that Pabban represented was market-ready and to be used on patients. *Id.*

The saline leaks posed a number of problems, including the inability to properly sterilize the Natrix System. *Id.* at ¶ 20. Not surprisingly, a medical device like the Natrix System must be sterilized before it can be used during an operation. *Id.* The process used to sterilize the Natrix System is known as "gamma radiation sterilization." *Id.* After sterilization, the product should show a "bioburden count" of less than 2000 "colony forming units" or CFU's. *Id.*

After the APA closed, the Natrix devices Pabban delivered to Kyphon were packaged individually in sealed trays. *Id.* at ¶ 21. The outside of each package bore the following label:

> Single use only. Do not reuse or resterilize.
> Sterile only if pouch is unopened and undamaged.

In addition, a "Product Information Data Sheet" was inside each sealed package. *Id.* That document provided, in part, as follows:

> The contents of the inner package (tray) are gamma sterilized. Contents are only sterile if the inner package is not open, damaged, or broken.

Kyphon opened the packages and tested whether the devices had been sterilized properly. *Id.* at ¶ 22. Kyphon's testing showed unacceptably high bioburden counts, which rendered the device unmerchantable. *Id.* Simply put, an unsterilized Natrix System could not be sold for use during an operation on a patient's spine. *Id.*

Kyphon raised the bioburden issue with Pabban. *Id.* at ¶ 23. On September 23, 2008, Pabban sent an email to Kyphon in which Pabban admitted that the bioburden problems were caused by the undisclosed saline leaks:

> I also spoke with Fred Weber (President of Sterility Assurance Laboratories) yesterday. I spoke to him about our bioburden issue on the delivery gun. He feels strongly that the saline exposure is the cause of the high bioburden counts. *Id.*

On September 17, 2008, Kyphon sent an email to Pabban complaining of the defects. *Id.* at ¶ 24. Pabban responded with an email on September 18, 2008, in which Pabban admitted that the devices were "unacceptable" and a "disappointment":

> … I agree that there has been some quality related issues that are unacceptable, and frankly a disappointment to me. *Id.*

In October 2008, Kyphon retained its own expert, SteriPro Labs, to perform bioburden testing. *Id.* at ¶ 25. SteriPro's report showed CFU's that were "too numerous to count," which means that the device was simply not sterilizable. *Id.*

Such a device presents a danger of serious injury or death and, therefore, cannot be sold. *Id.*

Prior to the closing of the APA, Kyphon reviewed documentation that showed Pabban was using 27.5 kilogray to sterilize the devices, when 25 kilogray should have been sufficient. *Id.* at ¶ 26. Kyphon asked Pabban why Pabban was using 27.5 kilogray. *Id.* Pabban responded that it did not know why. *Id.* After the closing, and after the bioburden problems were discovered by Kyphon, it again raised the issue with Pabban. *Id.* At that time, Pabban reluctantly acknowledged that Pabban had pre-closing bioburden problems that it failed to disclose to Kyphon. *Id.*

The defects in the Natrix System made the product dangerous and unmerchantable because they posed a serious and prohibitive risk to patients. *Id.* at ¶ 27. Therefore, on October 21, 2008, Kyphon terminated the Supplier Agreement with Syntech. *Id.* Syntech did not challenge the termination. *Id.*

Kyphon immediately began the process of correcting the defects. *Id.* at ¶ 28. That process included significant research and development efforts, followed by compliance testing and validation. *Id.* However, that process caused sales of the product to be delayed and Kyphon lost the "first to market" advantage that it sought and for which it paid. *Id.*

In September 2009, after an eleven month delay caused by the defects described herein, Kyphon launched the Kyphon Cement Delivery System. *Id.* at ¶ 29. Because of the delay, Kyphon lost substantial sales and market share, which reduced the value of the Natrix System by an amount in excess of $40 million. *Id.*

The APA provides a remedy for Pabban's failure to deliver the product it agreed to deliver. *Id.* at ¶ 30. By way of example, as set forth more fully below, Pabban represented and warranted to Kyphon and Medtronic, among other things, that the Natrix System was free from significant defects, suitable for its then current use, of merchantable quality, and suitable for its intended and labeled purpose. *Id.*

In Section 3.9 of the APA, Pabban warranted that:

> Title to and Condition of the Purchased Assets. Seller has full right, title and interest to the tangible Purchased Assets, free and clear of all Liens. The Purchased Assets . . . include all assets, properties, rights, interests and claims necessary for the conduct of the Business and all assets, properties, rights, interests and claim owned or controlled by Seller or an Affiliate of Seller that relate to the development, manufacture, commercialization or sale of products related to the Business. **The Purchased Assets (other than the Retained Assets or the Business Intellectual Property) are suitable for the uses for which they are presently used by Seller, in normal operating condition and free from any significant defects, ordinary wear and tear excepted.** The Purchased Assets include at least those assets listed on Schedule 3.1.1 through 3.1.4 (other than the Retained Assets). Except as specifically set forth on Schedule 3.9, all of the Purchased Assets are located at the facilities of Seller.

Id. at ¶ 31 (emphasis added).

In Section 3.16 of the APA, Pabban warranted that:

> Manufacturing Processes. Seller has delivered or made available to Kyphon or its Affiliates complete and accurate written documentation of the processes and procedures used or necessary to manufacture the Natrix System as it is currently conducted (the "Manufacturing Documentation"). **To Seller's Knowledge, the Natrix System, as presently designed and configured, and,**

> **when manufactured in accordance with the Manufacturing Documentation, will materially conform to the specifications established therefore and to Seller's Knowledge will be (a) of merchantable quality; (b) free from defects in design, material and workmanship; and (c) suitable for their intended and labeled purpose.**

Id. at ¶ 32 (emphasis added).

Section 7.1 of the APA mandates that Pabban indemnify Kyphon for all damages, including attorneys' fees, that result from Pabban's breach of the APA. *Id.* at ¶ 33. In addition, the APA grants Kyphon the right to withhold payments to Pabban based on Indemnifiable Losses, which include the breach of any representation or warranty of Pabban. *Id.* at ¶ 34. In particular, Section 7.3 of the APA provides, in pertinent part, that "Kyphon shall have the right to set-off any claims for Indemnifiable Losses . . . against any payments due and owing to Seller . . . and not yet paid." *Id.*

Pursuant to its rights under the APA, Kyphon justifiably withheld milestone payments that may have been otherwise due under the APA. *Id.* at ¶ 43. This lawsuit followed.

III
Argument

A. Kyphon's Allegations Must Be Accepted As True And Viewed In A Light Most Favorable To Kyphon

On a Rule 12(b)(6) motion, a claim may be dismissed "only if 'it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which

would entitle him to relief.'" *Cook v. Brewer*, 637 F.3d 1002, 1004 (9th Cir. 2011) (citations omitted). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. ___, 129 S.Ct. 1937, 1949 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 1237 S.Ct. 1955 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* In this case, Kyphon's counterclaim more than satisfies that pleading standard.

B. Kyphon's Breach of Contract Claim Is More Than Plausible

Pabban seeks to dismiss Kyphon's breach of contract claim because it is (1) implausible and therefore not entitled to the assumption of truth; (2) contradicted by extrinsic evidence; and (3) contrary to Sections 3.9 and 3.16 of the APA. None of these arguments have merit.

First, Pabban's claim that Kyphon's allegations are "conclusory" and therefore "not entitled to the assumption of truth" must be rejected. Pabban attempts to make this point by citing to selective portions of the counterclaim and reading those allegations in a vacuum. *See* Docket No. 49-1 (Motion) at 8. In doing so, however, Pabban ignores the first 35 paragraphs of the counterclaim, which describe in detail that contrary to Pabban's explicit contractual representations, the Natrix System was not "free from defects" because it leaked saline and was therefore unsafe for use on patients. *See* Docket No. 43 (Amended Counterclaim) at ¶¶ 17-20. These leaks were caused by weak seams or "welds" in the saline bag and a defect in the O-ring that sealed the bag to the device. *Id.* at ¶ 17. Pabban's failure to disclose these defects constitutes a breach of the APA, wherein Pabban represented that the Natrix System was "of merchantable quality," "free from defects in design, material and workmanship" and "suitable for [its] intended use and purpose." *Id.* at ¶ 32.

Pabban responds by claiming that Schedule 3.1.1 of the APA disclosed the saline leaks to Kyphon. This is simply not true. Schedule 3.1.1 contains a reference to a shelf life study, not saline leaks. Moreover, Schedule 3.1.1 says nothing about Pabban's failure to correct the O-ring problem and makes no mention of the serious contamination issues caused by the ongoing leaks. Instead, Schedule 3.1.1 articulates to the reader that Pabban discovered no problems associated with the O-ring design because a six month shelf life study had been "completed" with no negative results. In other words, rather than disclosing any problems, Schedule 3.1.1 suggests that the Natrix System would be ready for use with patients after sitting on a shelf for six months.

Pabban also suggests that the Performance Qualification Protocol ("PQP") referenced in paragraph 19 of the counterclaim disclosed the saline leaks to Kyphon.[1] Pabban ignores the fact, however, that the PQP is dated the *same day* the APA was signed and was only sent to Kyphon *after* Kyphon's due diligence was completed and the APA closed. *Id.* at ¶ 19. Moreover, the PQP is expressly contradicted by other documents provided by Pabban to Kyphon *before* the closing, including the DFMEA and PFMEA. *Id.* at ¶ 18. Those documents communicate that the pre-closing leaks associated with the saline bag and O-ring had been corrected and "closed" more than two months *before* the APA was signed. *Id.* In other words, rather than undermining Kyphon's concealment claim, the PQP proves that Pabban knew there were defects in the Natrix System and did not disclose those defects to Kyphon until after the APA closed.

Finally, Pabban argues that even if it failed to adequately disclose the defects in the Natrix System, it did not breach Section 3.9 or Section 3.16 of the APA.

[1] Kyphon does not object to the Court's consideration of the PQP as long as the Court takes judicial notice of *all* the documents referenced in the counterclaim, including the Design Failure Mode and Effects Analysis ("DFMEA") and Process Failure Mode and Effects Analysis ("PFMEA") described in paragraph 18. *See* Kyphon's Request for Judicial Notice.

Pabban's interpretation of those contractual provisions could not be more wrong. For example, Pabban incorrectly suggests that Section 3.9 applies only to intangible assets and not the Natrix System itself. This argument ignores the fact that the APA expressly defines "Purchased Assets" to include all assets necessary for the "commercialization of sale of the Natrix System." Clearly, one asset essential for the commercialization of any medical device is a design that enables the product to be used safely on patients. Similarly, Pabban's claim that Section 3.16 is inapplicable because Pabban did not fail to disclose a known defect is contrary to Pabban's own documents, including the DFMEA and PFMEA, as well as the fact that Pabban acknowledged it had bioburden problems only *after* the closing of the APA. As a result, no matter what the scenario, Kyphon's breach of contract claim is more than plausible and cannot be dismissed. *See Twombly*, 550 U.S. at 556, 127 S.Ct. 1955 (Rule 8 "does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence" to support the allegations).

C. Kyphon's Fraud Allegations Specifically Identify The False Statements Made By Herbert To Induce Kyphon To Purchase The Natrix System

Pabban seeks to dismiss Kyphon's fraud claim because Kyphon's fraud allegations are (1) implausible and therefore not entitled to the assumption of truth; (2) statements of opinion rather than fact; and (3) not plead with specificity. These arguments should be rejected.

First, Pabban's claim that Kyphon's fraud allegations are implausible because the APA did not require Pabban to disclose defects in the Natrix System makes no sense. As discussed above, Sections 3.9 and 3.16 of the APA cannot be read in the way Pabban desires under any scenario, let alone on a motion to dismiss.

Moreover, regardless of the terms of the APA, Pabban made false representations about the Natrix System in order to induce Kyphon to purchase a medical device Pabban's own records demonstrate was unsafe for use on patients. Among these misrepresentations, Pabban falsely claimed that the Natrix System was "production-ready" and on the verge of an imminent commercial release. *See* Docket No. 43 at ¶¶ 12-13. In truth, however, the Natrix System contained serious design defects that rendered it dangerous to use on patients – as the PQP provided by Pabban to Kyphon only *after* Pabban received more than $18 million demonstrates.

In fact, this argument is just the latest in a series of shifting theories Pabban has advanced in this case. Pabban's first amended complaint specifically alleges that before the APA was signed, the Natrix System was "ready for use with patients." *See* Docket No. 34 at 3:28. Now, however, Pabban acknowledges that it knew about defects in the Natrix System the day the APA was signed, but argues that it did not commit fraud because the APA disclosed those defects to Kyphon.

Pabban clearly wants the Court to adopt two sets of facts. For the purposes of its affirmative breach of contract claim against Kyphon, Pabban represents to the Court that the Natrix System was not dangerous and was ready for patient use. For the purposes of defending Kyphon's counterclaim, on the other hand, Pabban represents to the Court that it not only knew the Natrix System could not be sterilized and posed a danger to patients but that it fully disclosed that fact to Kyphon prior to the closing of the APA.

Of course, no such disclosure took place. Instead, prior to the closing of the APA, Pabban falsely stated both orally and in writing that the pre-closing leaks had been fixed. The truth about what Pabban actually knew was only revealed after the APA closed and Pabban provided Kyphon with the PQP. These are ample facts to render plausible Kyphon's allegation of fraud. *See Fecht v. Price Co.*, 70 F.3d 1078, 1083 (9th Cir. 1995) ("[A] complaint alleging that the plaintiff bought a house from

the defendant, that the defendant assured the plaintiff that the house was in perfect shape, and that the house was in fact built on landfill, would satisfy Rule 9(b).").

Pabban cannot escape liability for this conduct by alleging Herbert's false claims about the Natrix System were "statements of opinion" rather than fact. Herbert's claim that the Natrix System was "production ready" was an unequivocally false statement of fact. Moreover, as the creator of the Natrix System and CEO of Pabban, Herbert had superior knowledge about the Natrix System and therefore cannot hide behind the so-called "opinion exception" to fraud. *See Harazim v. Lynam*, 267 Cal.App.2d 127, 131 (1968) ("[W]hen one of the parties possesses, or assumes to possess, superior knowledge or special information regarding the subject matter of the representation . . . a representation made by the party . . . though it might be regarded as but the express of an opinion if made by any other person, is not excused if it be false."). In addition, because Herbert's statements falsely implied that the Natrix System had been extensively tested and was market ready, Pabban is liable for fraud no matter what the scenario. *Id.* at 133 (holding that if a statement of opinion "misrepresents the facts upon which it is based or implies the existence of facts which are nonexistent, it constitutes an actionable misrepresentation").

Finally, Kyphon's fraud claim is plead with more than enough specificity to satisfy Rule 9(b). There is no secret about who made the misrepresentations here, who he was acting for, or what the false statements were. Specifically, the source of the false statements was Herbert, acting on behalf of himself and the entities under his control, relating to the merchantability of the Natrix System. Contrary to the facts revealed by documents in Pabban's own files, Herbert falsely told Kyphon prior to the closing of the APA that the Natrix System was safe for use on patients and market ready. In addition, Herbert represented in writing that the Natrix System was "free from defects" and "suitable for its intended purpose." These representations, which are indisputably false, induced Kyphon to pay millions of dollars for a product it later discovered was not only unmerchantable, but dangerous to use on patients. In other

words, there is more than enough specificity in Kyphon's allegations to put Pabban on notice of the "who," "what" and "when" of the fraud. Moreover, Herbert's false claim that the Natrix System was "production ready" and on the verge of commercial release are more than sufficient to constitute the "how" of the fraud. *See Fecht v. Price Co.*, 70 F.3d 1078, 1083 (9th Cir. 1995) ("For purposes of Rule 9(b), allegations of specific problems undermining a defendant's optimistic claims suffice to explain *how* the claims are false."). In addition, documents dated prior to Kyphon's due diligence visit that state the pre-closing leaks were fixed, combined with documents dated the day of the closing of the APA that indicate those problems were far from cured, are more than sufficient to raise an inference of fraud. *Id.* at 1083 ("A plaintiff may also satisfy Rule 9(b) with allegations of circumstantial evidence if the circumstantial evidence alleged explains how and why the statement was misleading when made.").

D. Kyphon's Breach Of Good Faith And Fair Dealing Claim Is Valid And Medtronic's Claim For Declaratory Relief Cannot Be Dismissed

Pabban's remaining arguments are largely nonsensical. For example, Pabban alleges that Kyphon's breach of the covenant of good faith and fair dealing claim is not plead correctly because it "fails to specify the existence of any implied contractual obligation." Docket No. 49-1 at 24:9-10. Yet Kyphon clearly alleges that Pabban had both an express and implied obligation to disclose defects in the Natrix System that Pabban knew could potentially put the lives of patients at risk. By failing to do so, Kyphon breached not only the terms of the APA, but also the covenant of good faith and fair dealing implied by Delaware law. *See Glouser Holding Corp. v. U.S. Tape and Sticky Products, LLC*, 832 A.2d 116, 128-129 (Del. Ch. 2003) (holding in the context of an asset purchase agreement that a valid claim for breach of the covenant of good faith and fair dealing lies when the seller fails to disclose material information prior to the purchase).

Pabban's objection to Medtronic's declaratory relief claim is a similar "throwaway" argument. Contrary to Pabban's suggestion, Medtronic's declaratory relief claim does not ask the Court to determine whether or not Medtronic guaranteed Kyphon's obligations in the APA. Instead, Medtronic seeks a declaration that because of Pabban's conduct, it has no obligation to fulfill its obligation to guarantee Kyphon's milestone payments under the APA. In other words, Medtronic seeks a declaration that it does not owe Pabban any money under the circumstances – an issue Pabban clearly disputes and is therefore the proper subject of a declaratory relief claim. *See* Docket No. 34 at ¶¶ 55-64 (asserting declaratory relief claim against Kyphon relating to the milestone payments set forth in the APA).

IV

Conclusion

For the foregoing reasons, Pabban's motion to dismiss should be denied and Pabban should be required to answer the counterclaim without further delay.

DATED: July 18, 2011.

REED SMITH LLP

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